Complete Summary

GUIDELINE TITLE

Management of labor.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Management of labor. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Mar. 72 p. [126 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Management of labor. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Oct. 73 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Labor, including:

- Prodromal preterm labor
- Active preterm labor
- Preterm labor with rupture of membranes (ROM) or bleeding
- Vaginal birth after caesarean
- Failure to progress in labor

GUIDELINE CATEGORY

Evaluation
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the percentage of women with preterm labor (PTL) and/or preterm birth (PTB) who receive betamethasone appropriately
- To prevent unnecessary protracted labor with use of Treatment of Failure to Progress in Labor algorithm and annotations and its methods (e.g., timely monitoring)
- To increase the use of procedures that assist in progress to vaginal birth
- To increase the percentage of women who are assessed for risk status on entry to labor and delivery
- To increase the use of remedial techniques that resolve temporary non-reassuring heart tracing in labor
- To perform an appropriate evaluation for persistent non-reassuring heart rate tracing in labor before Caesarean section

TARGET POPULATION

All patients who present in labor

INTERVENTIONS AND PRACTICES CONSIDERED

1. Triage of symptoms of labor
2. Intrapartum care
3. Risk assessment for all patients in active labor including abnormal fetal heart rate, bleeding, breech presentation, fetal congenital heart disease, intrauterine growth retardation, maternal illness, and multiple gestation
4. Management of the third stage of labor including administration of uterotonic agents, controlled cord traction, and uterine massage after delivery of placenta, if appropriate

5. Management of signs/symptoms of preterm labor (PTL): medical evaluation (fetal fibronectin testing, sterile speculum exam, contraction pattern, determination of fetal well being, laboratory tests, and possible treatment)
6. Patient education for signs and symptoms of PTL
7. Management of critical events including betamethasone, plan for delivery, tocolysis, antibiotics, assay of phosphatidylglycerol in vaginal pool with or without amniocentesis, bed rest, monitoring of white blood cell count, fetal monitoring, other lab work as appropriate
8. Monitoring and management of prodromal PTL, such as observation, rechecks of cervix, bed rest, pelvic rest, transvaginal sonogram, fetal fibronectin monitoring
9. Management of active PTL
10. Management of vaginal birth after caesarean
11. Management of failure to progress in labor including management of arrest disorders (evaluation of the potential causes, artificial rupture of membranes, adequate analgesia, oxytocin augmentation, electronic monitoring of fetal heart tones and uterine contractions); management of protraction disorders; operative vaginal delivery or caesarean delivery
12. Intrapartum fetal heart rate monitoring (continuous electronic fetal monitoring, assessment and remedial techniques, vibroacoustic test or scalp stimulation, obstetrical or surgical consultation)
13. Emergent delivery in persistent non-reassuring heart rate tracings

MAJOR OUTCOMES CONSIDERED

- Risks associated with bacterial vaginosis and effects of antibiotic treatment
- Effectiveness of active management of labor in reducing caesarean deliveries
- Rate and type of delivery including spontaneous vaginal, forceps, or caesarean delivery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline annotation, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member groups during an eight-week review period.

Each of the Institute's participating member groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating member groups following implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group

Following the completion of the review period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the responses received from member groups. Two members of the Committee on Evidence-Based Practice carefully review the input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of four questions: (1) Is there consensus among all ICSI member groups and hospitals on the content of the guideline document? (2) Has the drafting work group answered all criticisms reasonably from the member groups? (3) Within the knowledge of the appointed reviewer, is the evidence cited in the

document current and not out-of-date? (4) Is the document sufficiently similar to the prior edition that a more thorough review (critical review) is not needed by the member group? The committee then either approves the guideline for release as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Member groups may introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three-six months. At the end of the pilot test phase, ICSI staff and the leader of the work group conduct an interview with the member groups participating in the pilot test phase to review their experience and gather comments, suggestions, and implementation tools.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Committee on Evidence-Based Practice reviews the revised guideline and approves it for release.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to "Summary of Changes Report – March 2007."

The recommendations for management of labor are presented in the form of seven algorithms with a total of 100 components, accompanied by detailed annotations. Algorithms are provided for: Management of Labor Main Algorithm, Management of Signs/Symptoms of Preterm Labor (PTL), Management of Critical Event, Monitoring and Management of Prodromal Preterm Labor, Vaginal Birth after Cesarean, Treatment of Failure to Progress in Labor, and Intrapartum Fetal Heart Rate Management. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) ratings and key conclusion grades (I-III, Not Assignable) are defined at the end of the "Major Recommendations" field.

Clinical Highlights

- Start appropriate treatment for the type of preterm labor involved as soon as possible after preterm labor is identified. Treatment should be based on specific symptoms as well as gestational age and condition of the mother and fetus. (Annotation #20)
- Women with preterm labor at appropriate gestational age should receive a single course of antepartum steroids to promote fetal lung maturity. (Annotations #32, 40, 45; for Annotations 32 and 40 -- refer to the original guideline document)

- Confirm active labor before admitting to facility evidenced by:
    - Spontaneous contractions at least 2 per 15 minutes, and two or more of the following:
        - Complete effacement of cervix
        - Cervical dilation greater than or equal to 3 cm
        - Spontaneous rupturing of membranes (SROM)

  (Annotation #5)

- Perform amniotomy early in labor if indicated as discussed in the guideline. (Annotation #11)
- Conduct frequent cervical checks (cervical checks afford best opportunity to detect labor progress and prevent failure to progress). (Annotation #11)
- Patient's level of risk should be assessed on presentation of active labor.
    - Oligohydramnios
    - Chronic and acute medical conditions of mother and/or fetus

  (Annotation #12)

- Augment with oxytocin to achieve adequate labor for 2 to 4 hours. (Annotation #80)
- If patient is in Stage II labor and is not making progress, initiate management of protraction disorders (positioning, fluid balance, oxytocin augmentation, obstetrical (OB)/surgical consult). (Annotation #86)
- Assure fetal well-being with either intermittent auscultation or continuous electronic fetal heart rate monitoring. (Annotation #11)
- When necessary initiate remedial techniques such as maternal position, intravenous (IV) fluid bolus and infusion, oxygen administration, discontinuing oxytocics, amnioinfusion, and subcutaneous terbutaline. (Annotation #95)
- Recognize and manage fetal heart rate non-reassuring patterns. (Annotation #96)

Management of Labor Main Algorithm Annotations

2. Triage for Symptoms of Labor

   Hospital and/or clinic triage for the labor patient will include these questions. Triage staff will assess general questions from OB experience. Some questions may require more details for assessment. Generally, the patient is encouraged to remain home as long as possible. The caregiver will manage any/all medical concerns according to accepted standards.

   General Questions:

   - Are you having contractions?
   - Is this your first baby?
   - Was your cervix dilated at least 2 to 3 cm on your last office visit?
   - Did you have medical complications during your pregnancy? Get specifics.
   - Are you at term? (What is your estimated date of conception?)

Specific Questions:

- Is your baby moving as usual?
  - If no, advise go to hospital.
- Has your water broken?
  - If yes, advise go to hospital.
- Are you bleeding?
  - If yes, advise go to hospital.
- Are you having unbearable contractions?
  - If yes, advise go to hospital.

When a patient presents to hospital and assessment shows the patient is NOT in labor: Patient education will include signs to look for, changes to assess, and reassurance that she can come back to the hospital when changes occur. When the caregiver prefers to hold and observe the patient, a reassessment must be conducted prior to release from the hospital.

5. Is Patient in Labor?

Labor is defined as:

Spontaneous contractions at least 2 per 15 minutes and at least two of the following:

- Complete effacement of cervix
- Cervical dilation 3 cm or greater (Cervical exam #1)
- Spontaneous rupturing of membrane (SROM)

Only patients who meet this definition of labor should be admitted for careful management of labor. Careful assessment of presenting patients is critical.

Patients who are not in labor should receive education that includes signs to look for, changes to assess, and reassurance that they can come back to the hospital when changes occur. (See Appendix B, "Patient Education Handout" in the original guideline document.) A patient may be placed on "hold" status for observation. Hold patients require medical reassessment before leaving the hospital.

If the patient's cervix is dilated less than 3 cm and oxytocin is started, this should be considered induction of labor, NOT augmentation of labor.

Evidence supporting this recommendation is of class: R

11. Intrapartum Care

See Institute for Clinical Systems Improvement (ICSI) Admission for Labor Order Set

Characteristics of care for a patient at time of admission to labor & delivery include:

- Chart evaluation
- Cervical exam #2
- Appropriate supportive care/comfort measures as per individual provider. May include, but are not limited to oral (PO) fluids, fluid balance maintenance, position changes, back rubs, music, ambulation, and tub bath/shower. Management of labor using patient care measures and comfort measures is supported. Documentation of progress of labor using a graphic medium is helpful to patient and staff.
- Adequate pain relief. This includes parenteral analgesics (e.g., nalbuphine hydrochloride [such as Nubain], butorphanol tartrate [such as Stadol], or hydroxyzine hydrochloride [such as Vistaril]) or epidural or intrathecal narcotics for patients in active progressing labor (continued dilation of the cervix).
- Documentation of progress of labor using a graphic medium (partogram) is started on admission.
- Monitor fetal heart rate. (See Intrapartum Fetal Heart Rate Management algorithm and annotations).
- Amniotomy unless contraindicated

  Amniotomy should be done early in labor unless spontaneous rupture has occurred or contraindications are present. Early amniotomy has been shown to be associated with a decrease in duration of labor and is part of the failure to progress protocol.

  Contraindications for amniotomy include:

  - Presentation unknown, floating, or unstable
  - Cervix dilated less than 3 cm
  - Patient refuses

Nurse Auscultatory Monitoring or Continuous Electronic Fetal Monitoring- External (EFM-ext)

Nurse auscultatory monitoring consists of auscultating with a DeLee stethoscope or a Doppler ultrasound device during a contraction and for 30 seconds after the contraction every 30 minutes during active stage of labor and every 15 minutes during second stage of labor for low-risk patient.

Seven randomized controlled studies have compared EFM to auscultation in both high-and low-risk patients and have shown no difference in intrapartum fetal death. Each study, except one, had dedicated one-on-one nurses assigned to each patient. The intrapartum death rate in the auscultated patients with one-on-one nursing was 0.4/1000. Most studies indicate a higher Caesarean delivery rate in those patients having EFM. The most recently published randomized controlled trial did show a significant reduction in perinatal deaths due to asphyxia in the electronically monitored group. It is not yet clear why this study differs from the others. Careful nurse monitoring can achieve high quality outcomes. Close nurse monitoring with a high nurse-to-patient ratio provides personalized high-quality obstetrical care. Each labor and delivery unit must staff itself to achieve the level of nurse staff to provide appropriate fetal monitoring. Where auscultation cannot be performed to the

American College of Obstetricians and Gynecologists (ACOG) standards, EFM is reasonable and preferable. However, EFM is not a replacement for well-trained, motivated, and caring nurses. The presence of a supportive and caring nurse adds quality to the obstetrical process and improves outcomes.

Pattern Is Clear and Reassuring Tracing?

When nurse auscultory monitoring yields an unclear fetal heart rate pattern, EFM is indicated. If the pattern remains unclear or if there are signs of persistent non-reassuring tracing, internal EFM may be necessary. If there is any question regarding possible decelerations on auscultation, do external fetal monitoring. If inconsistent tracing, do internal fetal monitoring.

Evidence supporting this recommendation is of classes: A, C, M, R

12. Any Concerns or Complications?

Risk assessment should be performed on all patients in active labor and is the responsibility of all members of the health care team. This includes, but is not limited to: nurses, midwives, and physicians. Patient is in active labor. (See Annotation #5, "Is Patient in Labor?" for specific definition.)

Initial assessments on entry into labor and delivery area:

- 20-minute fetal heart rate (FHR) assessment
- Patient assessment
- Prenatal risk review
- Risk in labor assessment

High-risk situations may include any of the following conditions:

- Abnormal fetal heart rate (see Intrapartum Fetal Heart Rate Monitoring algorithm annotations)
    - Situations that involve arrest or protraction disorders (see Failure to Progress algorithm annotations)
- Bleeding
- Breech presentation
- Dysfunctional labor
- Fetal congenital heart disease
- Intrauterine growth retardation
- Maternal congenital heart disease
- Maternal diabetes or gestational diabetes
- Maternal hypertension
- Maternal lupus
- Multiple gestation
- Oligohydramnios
- Other serious chronic and acute medical conditions of mother and/or fetus
- Oxytocin use
- Post date pregnancy (greater than or equal to 42 weeks, per physician discretion)

- Thick meconium

Evidence supporting this recommendation is of classes: A, M

14. Management of Third Stage of Labor

Active Management of the third stage of labor should be offered to women since it reduces the incidence of postpartum hemorrhage (PPH) due to uterine atony. Active management of the third stage of labor consists of interventions designed to facilitate the delivery of the placenta by increasing uterine contractions and to prevent PPH by averting uterine atony. The usual components include:

- Administration of uterotonic agents
- Controlled cord traction
- Uterine massage after delivery of the placenta, as appropriate

Evidence supporting this recommendation is of classes: M, R

Management of Signs/Symptoms of Preterm Labor (PTL) Algorithm Annotations

20. Assessment of Patient with Signs/Symptoms of Possible PTL

Be certain intervention is appropriate including certainty of gestational age. A sonogram should be considered if one has not been done.

A thorough medical evaluation should include the following:

- Fetal Fibronectin Testing

  Fetal Fibronectin Testing

  Testing for levels of fetal fibronectin (fFN) has been proposed as a way to predict preterm labor. Based on a review of the evidence, the ICSI Technology Assessment Committee concluded that:

  - Symptomatic at-risk patients with a negative test are highly unlikely to experience preterm delivery in the next 7 days; it is necessary to retest these patients to determine whether negative status is maintained.
  - Testing for fetal fibronectin is a safe procedure; the risks and limitations are related to the false negative rate and the false positive rate.
  - The clinical importance of a positive test remains unclear.
  - Testing for fetal fibronectin is not recommended as a screening test for asymptomatic patients, regardless of risk status.

  Patients with a negative test can expect pregnancy prolongation for the next 7 to 14 days without the need for expensive and uncomfortable intervention.

Check cervix and collect specimen for possible fFN if cervix appears less than 3 cm.

- Pelvic exam (PE)
- Sterile speculum exam (SSE)

Digital cervical exam should not be performed to confirm presentation in the presence of preterm rupture of membranes until imminent delivery is documented or required in the patient actively laboring (if a sonogram is unavailable). Delaying digital examination reduces infection.

Digital examination in the bleeding patient should be deferred until it is certain the patient does not have placenta previa.

Visualize cervix as well as possible to

- Rule out previa, abruption and non-obstetrical causes of bleeding such as cervical cancer
- Estimate dilation and effacement and obtain samples for gonorrhea, chlamydia and group B streptococcus (GBS)
- Perform bedside OB sonogram if feasible

This examination should include assessment of nitrazine (pH), pooling, and "ferning" (N,P,F) on an air-dried slide to check for amniotic fluid. This examination is also used to check for the non-uterine etiology of vaginal bleeding (e.g., a cervical lesion).

- Determine contraction pattern
- Determine fetal well-being (may include non-stress test [NST] and/or biophysical profile)
- Laboratory tests and possible treatment:
    - Urinalysis/urine culture (UAUC)
    - Consider culture swab of lower third of vagina and rectum for GBS.
    - Drug screen, even if previously screened and treated
    - Consider screening high-risk women with a history of at least one pre-term delivery for bacterial vaginosis. If positive, treatment should include oral metronidazole. Treatment of bacterial vaginosis infection in pregnant women at high risk for preterm delivery by traditional 7-day courses of therapy early in pregnancy appears to reduce preterm delivery. [Conclusion Grade II: See Conclusion Grading Worksheet A -- Annotation #20 (Bacterial Vaginosis) in the original guideline document] The evidence regarding treatment of low-risk, pregnant women with asymptomatic bacterial vaginosis is limited by use of inadequate therapy in the available studies. [Conclusion Grade Not Assignable: See Conclusion Grading Worksheet A -- Annotation #20 (Bacterial Vaginosis) in the original guideline document]
    - Consider cultures for gonorrhea and chlamydia

Consider nonintervention near term if gestational age is well documented. Do not inhibit labor where there is fetal or maternal jeopardy, fetal malformation, or death.

Evidence indicates prophylaxis with progesterone may decrease the reoccurrence of preterm labor in women with a history of one or more preterm births. See the National Guideline Clearinghouse (NGC) summary of the ICSI Routine Prenatal Care guideline.

Fish oil supplementation has not been found to be helpful in preventing preterm labor. One analysis of six clinical trials found an increase in intracranial hemorrhage among infants whose mothers took fish oil supplements during pregnancy compared to those who took olive oil.

Definition of Preterm Labor (PTL):

- Labor occurring after 20 and before 37 completed weeks; plus
- Clinically documented uterine contractions (4/20 minutes or 6/60 minutes); plus
- Ruptured membranes; or
- Intact membranes and cervical dilation greater than 2 cm; or
- Intact membranes and cervical effacement greater than 80%; or
- Intact membranes and cervical change during observation. These can be measured by changes in dilation or effacement, or by changes in cervical length measured clinically or by ultrasound.

Change in Status?

A change in status may be indicated by any of the following signs:

- Documented uterine activity (contractions or "irritability")
- Documented cervical changes
- Acute leakage of fluid from the vagina
- Sudden change in fundal height at prenatal visit
- Diagnosis of:
    - Multiple gestation
    - Third trimester bleeding
    - Infections (sexually transmitted infections [STIs], GBS, urinary tract infection [UTI], pyelonephritis, etc.)
    - Any other preterm risk condition

Patients who note warning signs should contact their health care provider for assessment as soon as possible. The patient should be seen by her provider within two hours of provider contact unless premature rupture of membrane (PROM) or bleeding is present in which case she should be seen as soon as is feasible. Although there is not a specific literature reference, the guideline team felt that the two-hour time frame is not only an acceptable goal, but an expected one.

Evidence supporting this recommendation is of classes: A, C, R

Management of Critical Event Algorithm Annotations

31. Cervix 5+ cm Dilated?

If cervix is dilated 5+ cm, the following emergency resuscitation protocol should be followed to determine whether transport is appropriate. In addition, the following protocol should be followed:

A. At 23 to 34 weeks administer first dose betamethasone immediately (STAT). Please refer to Annotation #45, "Possibly Initiate Tocolytics, Betamethasone and Antibiotic Group B Strep (GBS) Prophylaxis," for information on dosing of betamethasone and other corticosteroids.
B. Delivery of less than 24 weeks as previable.
C. Initiate tocolysis if possible. Please refer to Annotation #45, "Possibly Initiate Tocolytics, Betamethasone and Antibiotic Group B Strep (GBS) Prophylaxis," for more information on tocolysis.
D. Screening sonogram to rule out (R/O) gross anomaly, check presentation and placental abnormality.

35. Stabilize on Magnesium Sulfate (Tocolytics) / Transfer Mother to Appropriate Level of Care if Possible

Magnesium sulfate ($MgSO_4$) is generally given as a 4 gm IV bolus, then a 2 gm/hour IV infusion. If no IV access is available, magnesium sulfate can be given intramuscularly (IM) (5g IM in each buttock for a total of 10g) to stabilize a patient for transfer.

Patients with renal insufficiency require reduced dosages. If there is a clinical concern, magnesium levels should be checked. Therapeutic levels are 5 to 8 mEq/L.

Patients should retain deep tendon reflexes throughout the course of therapy. Flushing, "warmth" and nausea are common nuisance side effects.

Antiemetics are encouraged if nausea persists after the initiation of therapy.

Maternal transfer to prevent the need for premature neonatal transfer reduces preterm neonatal morbidity and mortality. Very low birthweight infants (less than 1500 grams) inborn to Level III perinatal centers have lower mortality, reduced incidence of Grade III and Grade IV intraventricular hemorrhage, and lower sensorineural disability rates than outborn infants.

Evidence supporting this recommendation is of class: C

37. Broad Spectrum Antibiotics

Broad-spectrum antibiotic coverage appears to lengthen the latency from preterm premature rupture of membranes (pPROM) until delivery and/or chorioamnionitis. Antibiotic therapy reduces maternal and neonatal morbidity in women with pPROM. There is no consensus on the choice of antibiotic or dose. A combination of ampicillin and erythromycin appears promising.

[Conclusion Grade II: See Conclusion Grading Worksheet B – Annotation #37 (Antibiotic Therapy) in the original guideline document]

Tocolysis should be considered in selected patients remote from term to delay delivery until transfer to a higher level of care.

Evidence supporting this recommendation is of classes: A, C, M, R

45. Possibly Initiate Tocolytics, Betamethasone and Antibiotic Group B Strep (GBS) Prophylaxis

Agents to be considered for tocolytic therapy include magnesium sulfate, terbutaline sulfate (including pump), indomethacin, and nifedipine. In February 1997, the Food and Drug Administration (FDA) alerted practitioners to use caution in the continuous subcutaneous administration of terbutaline sulfate.

The ICSI Technology Assessment #49, "Tocolytic Therapy for Preterm Labor" (available from the Institute for Clinical Systems Improvement Web site) states that studies of ritodrine, magnesium sulfate, and calcium channel blockers such as nifedipine, show that they may be equally effective in delaying delivery by 24 to 48 hours.

Other considerations for initial management of preterm labor include the following:

- Initiate betamethasone if 24 to 34 weeks gestation. Please refer to "Pharmacologic Management of Preterm Labor" below for more information on administration of betamethasone and other corticosteroids.
- Administer IV antibiotic effective against GBS until GBS results are back or if patient is known to be positive for GBS.
- Activity limitation as indicated.
- Consider indomethacin. The addition of indomethacin should ONLY be used at less than 32 weeks and only for 72 hours maximum. Gestation – additional studies assessing the potential risks of indomethacin tocolysis are needed before it is used as a first-line tocolytic therapy
- Order additional laboratory analysis pertinent to tocolytic being used.

Although use of magnesium sulfate as a tocolytic is nearly universal, a recent concern regarding safety has been expressed.

Evidence supporting this recommendation is of classes: B, M, R

Pharmacologic Management of Preterm Labor

A. Tocolysis and Betamethasone

Management of Preterm Labor should include parenteral tocolysis for 48 hours with administration of 2 doses of betamethasone.

The usual dosage regimen is betamethasone 12 mg IM STAT, then repeat in 24 hours.

An alternative medication is dexamethasone for a total of 24 mg (usual dosing regimen is 6 mg IM every 12 hours times four doses).

Treatment should be initiated in women with any symptoms or signs which might herald the onset of preterm delivery or a potential need for elective birth, rather than waiting until the diagnosis is in no doubt. While a single complete course of antenatal steroids provides significant multiple benefits to the preterm neonate, multiple courses should not be used.

Treatment should not be withheld because delivery appears to be imminent.

Antenatal corticosteroid therapy for fetal lung maturation reduces mortality, respiratory distress syndrome, and intraventricular hemorrhage in preterm infants. These benefits extend to a broad range of gestational ages and are not limited by gender or race. New data indicate that the benefits of postnatal surfactant are enhanced by antenatal corticosteroid administration. No adverse consequences to a policy of administration of antenatal steroids to women in preterm labor have been identified.

The beneficial effects of corticosteroids are greatest more than 24 hours after beginning treatment. However, treatment less than 24 hours in duration may improve outcome. Every effort should be made to treat women before spontaneous or elective preterm delivery.

B. Administer Antibiotic for GBS Prophylaxis Until GBS Results Are Back

Please refer to the GBS prophylaxis guidelines at your institution.

Attempt to Discontinue Tocolysis

If persistent mild uterine activity continues, consider nifedipine. For more information on tocolysis, please refer to ICSI Technology Assessment # 49, "Tocolytic Therapy for Preterm Labor."

Aggressive Management with Tocolysis

Tocolysis should be continued if necessary until fetal lung maturity is documented or maternal or fetal complications arise for which preterm delivery is indicated.

The etiology of preterm labor remains obscure. Consequently, patients who continue to have regular uterine activity and/or gradual cervical changes on parenteral tocolysis must be managed with clinical judgment balancing the

risks to the mother of ongoing tocolysis against the risks of preterm birth for the neonate.

The use of more than a single tocolytic agent greatly increases the risks to the mother and should be undertaken only by experienced obstetric specialists in well-selected cases. An ICSI Technology Assessment Committee concluded the following regarding management of preterm labor with tocolytic therapy:

- The effectiveness of magnesium sulfate, nifedipine, and ritodrine is comparable when used to delay delivery for 24 to 36 hours. This delay would enable the administration of corticosteroids and/or transfer of the patient to a tertiary care center. The side effect profiles do differ and should be considered when a tocolytic agent is to be used.
- Long-term tocolysis after a successful acute administration of a tocolytic has not been found to be effective in preventing preterm birth or reducing the risk of recurrent preterm labor.
- With appropriate selection and monitoring, tocolytic therapy is a relatively safe procedure. Although side effects are generally minor, they can be major and life threatening, including pulmonary edema, cardiac arrest, and death.
- Administration of pharmacologic tocolysis is a complicated procedure that should only be undertaken in an intensive care setting by those familiar with the implications and potential complications.

Terbutaline Pump

Several well-designed studies have concluded that terbutaline administered by infusion pump may be a safe and effective treatment option for the prolongation of pregnancy. However, there continues to be debate in the medical literature concerning the safety and efficacy of the pump.

Another study concludes that continuous subcutaneous terbutaline infusion was associated with an extremely low incidence of serious events.

Evidence supporting this recommendation is of classes: A, B, C, D, M, R

47. Vaginal Pool ± Amnio at 32+ Weeks for Fetal Lung Maturity (FLM)

Phosphatidyl glycerol (PG) is a reliable indicator of fetal lung maturity if present in vaginal pool specimens. Lecithin-sphingomyelin (L/S) ratio is unreliable if blood and/or meconium are present in the fluid. Certain assays of phosphatidylglycerol (PG) may be influenced by the presence of heavy growth of Gardnerella vaginalis. Please consult with your local hospital clinical laboratory.

Evidence supporting this recommendation is of class: R

49. Management of Preterm Labor with Bleeding

In the presence of preterm labor with bleeding, IV access is essential.

- The patient should be on strict bedrest.
- Blood should be typed and crossmatched.
- Complete blood counts (CBCs) with platelets, prothrombin time (PT), partial thromboplastin time (PTT), and fibrinogen
- Continue fetal monitoring while bleeding

53. Deliver for: Eventual FLM/Fetal Distress/Chorioamnionitis/Active Labor/37 Weeks No PROM/37 Weeks PROM/Other Obstetrical Indicators

Under these conditions, the work group recommends delivery.

Monitoring and Management of Prodromal Preterm Labor Algorithm Annotations

58. Bedrest and Pelvic Rest for 48 Hours and Administer Betamethasone if High Risk for Preterm Delivery and 23 to 34 Weeks

A full OB sonogram should be done if no recent OB sonogram results are readily available and if no cervical change is indicated on the second cervical check.

- Bedrest or pelvic rest for 48 hours

  The number of hours of bedrest (during the day or complete bedrest with bathroom privileges) needs to be determined based upon risk of preterm labor and patient's environment. Bedrest and careful IV or oral (PO) hydration may be sufficient to stop some episodes of preterm labor.

- Administer betamethasone if the patient is between 23–34 weeks gestation and at high risk for preterm delivery. See Annotation #45 "Possibly Initiate Tocolytics, Betamethasone and Antibiotic Group B Strep (GBS) Prophylaxis," for information on dosing of betamethasone and other corticosteroids.

Management of prodromal labor should include close observation with a recheck of the cervix one to two hours after initial check. The following steps may be indicated.

- Urinalysis
- Hydration if indicated
- Fetal monitoring
- Take steps to reduce uterine irritability such as reduced physical activity, no exercise, lifting, household or yard activity, and no orgasm, intercourse or nipple stimulation.

Previous preterm delivery, myomectomy and multiple gestation are risk factors of particular concern.

Evidence supporting this recommendation is of classes: A, R

59. Consider Transvaginal Sonogram (if Available) for Cervical Length

Transvaginal sonogram (TVS) for cervical length is under active investigation for monitoring of patients with sign/symptoms of preterm labor and early cervical change. Cervical length of less than or equal to 25 mm (18 to 30 mm) or a rapidly thinning cervix correlate with increased preterm birth rates.

61. Continue Intensive (at Least Weekly) Follow-Up Until 34 Weeks Plus 6 days/Consider Betamethasone (23 to 34 Weeks)

Patients who test positive for fFN might be more likely to benefit from aggressive therapy, closer surveillance, and corticosteroid administration to decrease the complications associated with preterm birth.

65. Continue Monitoring Fetal Fibronectin

If fFN is negative, reassure patient and continue monitoring fFN weekly or every two weeks until 34 weeks plus 6 days as long as symptoms persist.

Patients who have a negative fFN have a less than one-percent chance of preterm labor in the next 7 days. The patient will need to be retested to assess the subsequent risk of preterm labor. Please refer to ICSI Technology Assessment #47, "Fetal Fibronectin for the Prediction of Preterm Labor" (available from the Institute for Clinical Systems Improvement Web site)

Vaginal Birth After Caesarean Algorithm Annotations

71. Special Considerations of Labor Management
    - Availability of team capable of performing a Cesarean delivery within a short time.
    - Intermittent auscultation or continuous electronic fetal heart rate monitoring should be done. See Intrapartum Fetal Heart Rate Management algorithm annotations.
    - Augmentation or induction of labor with oxytocin increases the risk of uterine rupture
    - The use of prostaglandins for induction or cervical ripening is not recommended because it increases the risk of uterine rupture.
    - Uterine scars do not require manual exploration postpartum.
    - There is no evidence that epidural anesthesia is contraindicated in patients with previous low segment transverse Cesarean delivery.
    - Amnioinfusion is not contraindicated.
    - After review of 76 cases, 39 of which were monitored with intrauterine pressure catheters (IUPCs), the usefulness of IUPCs in making the diagnosis of uterine rupture is not supported.

Evidence supporting this recommendation is of class B, C, D, R

74. Complicated Labor Management

The same considerations for intervention in labor apply to vaginal birth after cesarean sections (VBACs) as for other attempted deliveries.

Complicated labor can be manifested in several categories:

- Failure to progress – The same considerations for intervention, including amniotomy, oxytocin, epidural anesthesia/analgesia, apply to VBACs. If indication for primary Caesarean was dystocia, percentage successful VBAC was 77%. Women who required oxytocin for induction had 58% successful vaginal delivery versus 88% who required oxytocin for augmentation.
- Fetal distress - See Intrapartum Fetal Heart Rate Management algorithm annotations.
- Maternal Complications - Pre-eclampsia and exacerbation of pre-existing maternal illness are managed similarly in complicated VBAC versus complicated vaginal labor patient.
- Uterine rupture - The scarred uterus has an increased potential to rupture. Uterine rupture occurs in between 1/100 and 1/11,000 deliveries depending on whose data one uses and the clinical presentation. The type of scar makes a difference in frequency of rupture and severity of symptoms also (low segment transverse [LST] 0.2–0.8 Classical 4.3 to 8.8, T4 .3 to 8.8, Low Vertical 0.5 to 6.5).

  Rupture through a low segment transverse scar is much more likely to go undetected or produce maternal hypovolemia or gradual fetal distress. Complete rupture with expulsion of fetus or placenta is a true obstetric emergency and can lead to maternal or hypovolemic complication, even death, as well as fetal hypoxia and death.

Conditions that increase the risk for uterine rupture:

- Previous uterine injury, Caesarean delivery, myomectomy, etc.
- Trauma during pregnancy - hyperstimulation, difficult forceps, internal podalic versions, fundal pressure, etc.
- Uterine defects not related to trauma (e.g., congenital defect, invasive mole)
- More than one previous Caesarean delivery

Signs and symptoms of uterine rupture include:

- Fetal distress - 50% to 70% of detected ruptures present with abnormal fetal heart (FH) tracings (i.e., variable decelerations that evolve into late decelerations)
- Uterine pain, especially pain over previous incision that continues between contractions
- Hemorrhage - intra-abdominal, vaginal, or urinary
- Palpation of fetal parts
- Loss of contractions
- Recession of presenting part
- Fetal death

Uterine scar disruptions can be classified into three types:

- Scar dehiscence - Opening of previous scar, with intact overlying peritoneum (uterine serosa) no expulsion of uterine contents
- Incomplete rupture - Opening of previous scar, but not overlying peritoneum, extraperitoneal extrusion of intrauterine contents
- Complete rupture - Opening of previous scar and overlying peritoneum with extrusion of intrauterine contents into peritoneal cavity

Evidence supporting this recommendation is of classes: C, D, R

Treatment of Failure to Progress in Labor Algorithm Annotations

79. Less than 1 cm Dilation x Two Consecutive Hours?

Labor progress is measured in dilation of the cervix. The only way to make this assessment is to do cervical checks. Cervical checks should indicate at least 1 centimeter dilation per hour. Frequent cervical checks afford the best opportunity for detection of failure to progress.

At least one clinical trial testing the effectiveness of active management of labor in reducing Caesarean deliveries has used one-hour checks; others have used two-hour checks. Consider the effects of medication on progress of labor and effects on the fetus. The "two-hour" rule for determining dilatation has been challenged. However, there is not enough supporting evidence to change the working group's recommendation of "one-hour" cervical checks.

Evidence supporting this recommendation is of classes: A, C, R

80. Management of Arrest Disorders

Failure to progress is defined as cervical changes of less than 1 cm per hour for 2 consecutive hours. Active management of labor does not reduce the rate of Caesarean delivery but may decrease the length of labor and increase patient satisfaction in nulliparas. [Conclusion grade II: See Conclusion Grading Worksheet C -- Annotation #80 (Management of Arrest Disorders) in the original guideline document].

The sequence of management of arrest disorders includes:

1. Evaluation of the potential causes (check adequacy of labor with internal monitor). Adequate contractions are counted as a minimum of 200 montevideo units per 10-minute blocks of time over a 2-hour time period.
2. Artificial rupture of membranes if membranes are intact and there are no contraindications.
   (See Annotation #11, "Intrapartum Care.")
3. Ensure adequate analgesia as deemed appropriate by care provider.
4. Oxytocin augmentation according to hospital protocol.

Contraindications include:

- Unknown presentation or floating/unstable

- Patient refusal
- Inability to monitor contractions adequately

Electronic monitoring of fetal heart tones and uterine contractions is necessary when oxytocin is administered. Refer to Main Algorithm, Annotation #11, "Intrapartum Care," for criteria to guide discontinuance of oxytocin augmentation.

Because of the risk of uterine hyperstimulation, an intrauterine pressure catheter should be encouraged in conjunction with a high-dose oxytocin protocol.

Uterine hyperstimulation is defined as contractions lasting longer than 90 seconds, or more than five contractions in 10 minutes. Contractions can be managed by changing the maternal position and administering oxygen, shutting off the pitocin until recovery has occurred, and possibly the administration of terbutaline 0.25 mg subcutaneously.

5. Obtain an obstetrical/surgical consult if necessary. Caesarean delivery is done when patient is not making progress for 2 to 4 hours (regardless of oxytocin dosage or duration of oxytocin) after adequate contraction pattern has been achieved on maximum oxytocin dose appropriately used. Although studies of single aspects of active management have not demonstrated a decrease in the rate of Caesarean delivery, an analysis of the literature suggests that some combination of active management techniques will lead to an overall decrease in the rate of Caesarean delivery.

Evidence supporting this recommendation is of classes: C, M, R

82. Caesarean Delivery

After evaluating these options, caregiver will perform a Caesarean delivery when necessary. Education for vaginal birth after Cesarean trial of labor is given before discharge.

84. Less than 1 cm Descent per Hour?

When patient has reached Stage II labor, a reassessment at least every 30 minutes x 2 is done to assess descent of the fetus and rotation of the fetus. If the patient is making appropriate progress, the caregiver can anticipate vaginal delivery. Fetal descent should be greater than 1 cm per hour.

If patient is not progressing, consider internal monitor to measure strength of uterine contractions. After 2 hours of internal monitoring there should be enough evidence to determine if patient is making progress.

Relative contraindications to direct, invasive monitoring include chorioamnionitis, active maternal genital herpes infection and human immunodeficiency virus (HIV) infection, certain fetal presentations, and

conditions that preclude vaginal examinations such as placenta previa or undiagnosed vaginal bleeding.

Evidence supporting this recommendation is of class: R

86. Management of Protraction Disorders

If the patient in Stage II labor is not making progress, management of protraction disorders will include:

- Evaluation of maternal position and fetus position. Consider having the patient move into different positions.
- Evaluation of fluid balance
- Oxytocin augmentation for failed Stage II unless contraindicated. (See Annotation #80, "Management of Arrest Disorders.")
- OB/surgical consult if necessary

Evidence supporting this recommendation is of classes: B, R

88. Operative Vaginal Delivery Contraindicated?

When above measures fail, the caregiver will consider operative vaginal delivery including vacuum extraction or mid/low forceps delivery unless contraindicated. Vacuum extraction contraindications include:

- Presenting part is too high.
- Provider is inexperienced.
- Fetal distress with inability to do timely operative vaginal delivery
- Patient refusal

Note: When using vacuum extraction or forceps application with a suspected macrosomic infant, be aware of the risk of shoulder dystocia.

There is some evidence to suggest that it is safe to wait to intervene until after 4 hours of adequate labor with progress in absence of fetal distress.

Evidence supporting this recommendation is of classes: C, D, R

Intrapartum Fetal Heart Rate Monitoring Algorithm Annotations

91. Continuous Electronic Fetal Monitoring-External (EFM-ext) or EFM-Internal (int) (if needed)

Electronic fetal monitoring (EFM) is indicated in all high-risk situations and in low-risk situations when the auscultatory pattern is unclear or when 1:1 nursing staff is not available. Internal EFM may allow easier patient positioning and promote patient activity by being less confining than external EFM. Low-risk patients should be encouraged to be as active and mobile as possible.

95. Assessment and Remedial Techniques

A persistently non-reassuring fetal heart rate (FHR) tracing requires evaluation of the possible causes. Initial evaluation and treatment may include:

- Discontinuation of any labor stimulating agent
- Cervical examination to assess for umbilical cord prolapse or rapid cervical dilation or descent of the fetal head
- Changing maternal position to the left or right lateral recumbent position, reducing compression of the vena cava and improving uteroplacental blood flow
- Monitoring maternal blood pressure level for evidence of hypotension, especially in those with regional anesthesia (if present, treatment with ephedrine or phenylephrine may be warranted)
- Assessment of patient for uterine hyperstimulation by evaluating uterine contraction frequency and duration
- Amnioinfusion – indications for therapeutic amnioinfusion include repetitive severe variable decelerations and prolonged decelerations. Amnioinfusion for thick meconium is no longer recommended.

Evidence supporting this recommendation is of classes: A, R

96. Reassuring Fetal Heart Rate (FHR) Pattern Now?

All obstetrical nurses, nurse midwives, and physicians must achieve competence and confidence in fetal heart rate monitoring and FHR pattern analysis. The following patterns must be recognized and managed appropriately:

- Late decelerations are a gradual decrease and return to baseline of the fetal heart rate associated with a uterine contraction. The deceleration's onset, nadir and termination are coincident with the onset, peak, and termination of the contraction. Late decelerations indicate possible uteroplacental insufficiency and imply some degree of fetal hypoxia. Repetitive late decelerations and late decelerations with decreased baseline variability are non-reassuring.
- Variable decelerations are an abrupt decrease in FHR below the baseline. The decrease is greater than or equal to 15 beats per minute (bpm), lasting equal to or greater than 15 seconds and less than two minutes from onset to return to baseline. The onset, depth, and duration of variable decelerations commonly vary with successive uterine contractions. Variable decelerations are non-reassuring when the FHR drops to less than 70 bpm, persists for at least 60 seconds from the beginning to the end of the variable deceleration, and is repetitive. The pattern of variable deceleration consistently related to the contractions with a slow return to FHR baseline is also non-reassuring.
- Tachycardia is a FHR greater than 160 bpm. Fetal tachycardia may be a sign of persistent non-reassuring tracing when it lasts longer than 10 minutes and is associated with decreased variability.
- Moderate bradycardia is a FHR less than 110 bpm, and is often associated with fetal head compression. Severe bradycardia (less than

80 bpm) lasting longer than 3 minutes is an ominous finding and may be associated with fetal acidosis.

- A sinusoidal pattern of regular oscillation of the baseline long-term variability with absent short-term variability is an ominous sign that may indicate fetal compromise.
- Prolonged deceleration is a decrease in FHR below the baseline of 15 bpm, lasting 2 minutes but less than 10 minutes from onset to return to baseline. A prolonged deceleration of 10 minutes or more is considered a change in baseline. Prolonged deceleration can be caused by any mechanism that leads to fetal hypoxia.

Evidence supporting this recommendation is of classes: D, R

99. Further Fetal Assessment Reassuring?

Obtain obstetrical or surgical consultation or referral where needed to plan for operative delivery if there are any non-reassuring FHR patterns present. Consider contacting a neonatology team to plan for possible neonatal intervention.

Reassuring results: 15 bpm increase for 15 seconds from beginning to end of acceleration in response to scalp stimulation or to vibration or sound. Fetal scalp blood sampling for pH may be used to assess a nonreassuring fetal heart rate pattern. Scalp pH greater than 7.19 is a positive result.

Scalp pH or other fetal assessment may be performed according to each medical group's established practice. Fetal pulse oximetry is an emerging technology whose benefit is yet unproven. [Conclusion Grade III: See Conclusion Grading Worksheet D -- Annotation #99 (Further Fetal Assessment Reassuring) in the original guideline document].

If the scalp stimulation test or vibroacoustic test is non-reassuring then immediate delivery is indicated. Other tests to assess fetal status may be helpful if available. This includes fetal scalp sampling to determine fetal acid base status. However, proper FHR pattern interpretation and the use of scalp stimulation or vibroacoustic stimulation can allow the clinician to detect persistent non-reassuring tracing.

Evidence supporting this recommendation is of classes: A, D, M

100. Emergent Delivery

Persistent non-reassuring tracings indicate the need for emergent delivery. Delivery should be affected by appropriate means depending on the clinical situation. This may include vacuum extraction, forceps, or Caesarean delivery, depending upon fetal presentation and the expertise of the attending physician(s).

Caesarean delivery should be performed if vacuum extraction or forceps are inappropriate for use.

If a Cesarean delivery is performed, the suitability of a VBAC in a subsequent pregnancy should be discussed with the patient.

The following are indications for Cesarean birth based on abnormal FHR monitoring according to the Minnesota Clinical Comparison and Assessment Project:

- Late decelerations which comprise the majority of contractions over a minimum 20-minute period in the absence of adequate beat-to-beat variability and which do not respond to remedial techniques
- Severe variable decelerations which comprise the majority of contractions over 20 to 60 minutes and which do not respond to remedial techniques
- Severe persistent non-remediable bradycardia
- Scalp pH less than 7.2 or negative FHR acceleration test (confirmation in 15 to 20 minutes recommended)
- There may be other combinations or non-remediable patterns that may not meet severity criteria listed above that may be indications for preparation for Caesarean birth. A scalp pH or FHR acceleration test (scalp or acoustic) may help clarify the issue. Consultation or second opinion is suggested.
- In the second stage of labor, depending on the judgment and skill of the physician, operative vaginal delivery may be the least hazardous for the mother and child.

If one-minute APGAR is less than three, or five-minute APGAR is less than six, cord pH or gases are recommended. Cord pH is a better indicator than APGAR for fetal compromise. A segment of umbilical cord is isolated with clamps and may be stored up to 60 minutes after delivery with reliable umbilical artery pH determination. The segment does not need to be heparinized or placed on ice.

Evidence supporting this recommendation is of class: D

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for:

- Management of Labor
- Management of Signs/Symptoms of Preterm Labor (PTL)
- Management of Critical Event
- Monitoring and Management of Prodromal Preterm Labor
- Vaginal Birth after Cesarean
- Treatment of Failure to Progress in Labor
- Intrapartum Fetal Heart Rate Management

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of labor, including:

- Increased percentage of women with preterm labor who receive betamethasone appropriately
- Appropriate management of protraction disorders
- Increased use of procedures that assist in progress to vaginal birth and remedial techniques that resolve temporary non-reassuring heart tracing in labor
- Increased percentage of women who are assessed for risk status on entry to labor and delivery
- Appropriate evaluation for persistent non-reassuring heart rate tracing in labor before Caesarean section

POTENTIAL HARMS

Side Effects of Pharmacologic Management

- In February 1997, the Food and Drug Administration (FDA) alerted practitioners to use caution in the continuous subcutaneous administration of terbutaline sulfate
- Although the side effects of tocolytic therapy are relatively minor, they can be major and life threatening, including pulmonary edema, cardiac arrest, and death. Flushing, "warmth" and nausea are common nuisance side effects of the use of magnesium sulfate. The use of more than a single tocolytic agent greatly increases the risks to the mother and should be undertaken only by experienced obstetric specialists in well-selected cases.
- Oxytocin increases the risk of uterine rupture. Because of the risk of uterine hyperstimulation, an intrauterine pressure catheter should be encouraged in conjunction with a high dose oxytocin protocol.

False Test Results

The risks and limitations of testing for fetal fibronectin (fFN) are related to the false negative rate and the false positive rate.

Vacuum Extraction/Forceps Application

When using vacuum extraction or forcep application with a suspected macrosomic infant, be aware of the risk of shoulder dystocia.

Uterine Rupture During Vaginal Birth After Caesarean

The scarred uterus has an increased potential to rupture. Uterine rupture occurs in between 1/100 and 1/11,000 deliveries depending on whose data one uses and the clinical presentation. The type of scar makes a difference in frequency of rupture and severity of symptoms also (low segment transverse). Rupture through a low segment transverse scar is much more likely to go undetected or produce maternal hypovolemia or gradual fetal distress. Complete rupture with expulsion of fetus or placenta is a true obstetric emergency and can lead to maternal or hypovolemic complication, even death, as well as fetal hypoxia and death.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to amniotomy include:

- Presentation unknown, floating, or unstable
- Cervix dilated less than 3 cm
- Patient refuses

Contraindications to oxytocin augmentation include:

- Unknown presentation or floating/unstable
- Patient refusal
- Inability to monitor contractions adequately

Relative contraindications to direct, invasive monitoring include:

- Chorioamnionitis
- Active maternal genital herpes infection and human immunodeficiency virus (HIV) infection
- Certain fetal presentations and conditions that preclude vaginal examinations such as placenta previa or undiagnosed vaginal bleeding

Vacuum extraction contraindications include:

- Presenting part is too high.
- Provider is inexperienced.
- Fetal distress with inability to do timely operative vaginal delivery
- Patient refusal

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- The recommendations in this guideline are supported by large controlled studies. The guideline work group would prefer to refer to double-blind studies, but it is not feasible to blind a woman to whether she is having labor or delivery. It is unsafe to blind care providers to whether a woman has had a previous Cesarean delivery or not or previous labor and delivery complications. It is also unsafe to blind providers to whether persistent non-reassuring heart rate tracings have occurred. Given these limitations, the work group feels confident of the literature support for the recommendations within this guideline. Furthermore, these recommendations are consistent with the latest practice patterns published by the American College of Obstetricians and Gynecologists (ACOG).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Management of labor: percentage of women in the guideline population who have spontaneous rupture of membranes (SROM) or early amniotomy.
- Management of labor: percentage of women in the guideline population with failure to progress diagnosis who have oxytocin.
- Management of labor: percentage of women who are assessed for risk status on entry to labor and delivery.
- Management of labor: percentage of births with amnioinfusion when either of the following is present: thick meconium or repetitive severe variable decelerations or oligohydramnios.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

Safety
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Management of labor. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Mar. 72 p. [126 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Oct (revised 2007 Mar)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

SOURCE(S) OF FUNDING

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: John Jefferies, MD (Work Group Leader) (Mayo Clinic) (OB/Gyn); Leslie Atwood, MD (Allina Medical Clinic) (Family Medicine); Lori Bates, MD (Mayo Clinic) (Family Medicine); Brendon Cullinan, MD (Hennepin County Medical Center) (Family Medicine); Mark Matthias, MD (Mankato Clinic) (Family Medicine); Amy Knox, CNM (Park Nicollet Health Services) (Nurse Midwife); Cherida McCall, CNM (HealthPartners Medical Group) (Nurse Midwife); Brielle Stoyke, CNM (CentraCare) (Nurse Midwife); Ruth Wingeier, CNM (CentraCare) (Nurse Midwife); Jenny Senti, APRN (Altru Health System) (Nursing); Dale Akkerman, MD (Park Nicollet Health Services) (OB/Gyn); Leslie Pratt, MD (Park Nicollet Health Services) (Perinatal Medicine); Peter VanEerden, MD (Sioux Valley Hospitals) (Perinatal Medicine); Nancy Jaeckels (Institute for Clinical Systems Improvement) (Implementation Advisor); Linda Setterlund, MA, CPHQ (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflict of interests to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at http://www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Management of labor. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Oct. 73 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Management of labor. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2007 Mar. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- Order set: admission for routine labor. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2007 Mar. 4 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

Appendix B of the original guideline document includes a patient education handout on active management of labor.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on December 14, 2005. This NGC summary was updated by ECRI Institute on May 24, 2007.

COPYRIGHT STATEMENT

If the abstracted ICSI Guidelines are downloaded by an organization, copies may be distributed to the organization's employees but may not be distributed outside of the organization without the prior written consent of the Institute for Clinical Systems Improvement, Inc.

All other copyright rights in the abstracted ICSI Guidelines are reserved by the Institute for Clinical Systems Improvement, Inc. The Institute for Clinical Systems Improvement, Inc. assumes no liability for any adaptations or revisions or modifications made to the abstracts of the ICSI Guidelines.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 10/8/2007